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(54) Internal shield for a vascular anastomosis

(57) The device, which purpose is such internal shielding of a vascular anastomosis, that the undesirable perivascular vibration is avoided, is created from a stiff, eventually moderately elastic, non-resorbable, biologically inert, unmoistenable and sterilizable material and has the form of the uncomplete tube (4), which length is minimally five times larger than the diameter of the targeted vessel or substitute and this uncomplete tube (4) is in the third and fourth fifth of its length counter to the course of blood flow provided with the orifice (5) wide minimally one quarter of the circumference of the tube, while from the apical end of the orifice (5) or from the rear end of the said orifice (5), or both, grows up gradually tapered tongue-like structure (6) or similar tongue-like tapered structure (10) or both, while these structures are moderately bow- like curved externally, like the margin (8) of the orifice (5) and all margins of the device are blunt and the whole internal surface of the device is highly polished.

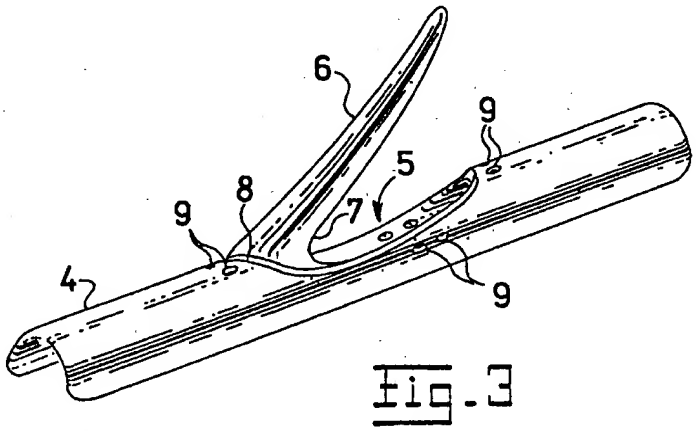

Fig. 3

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Description

The field of the technique

The internal shield of an anastomosis in accordance with the invention solves the problem of the origin of so called intimo-medial hyperplasia, which quite often develops in an anastomosis in vascular system, particularly in the case of vascular reconstructions of smaller calibre, and leads up to the resulting occlusion of the said reconstruction.

The present state of the technique

The anastomosis in the vascular system is basically an arteficially created connection either of proper vessels, either of a vessel and a biological or arteficial arterial substitute and most commonly is executed by suturing with the use of a special suturing material. Such anastomosis can be created in any part of the vascular system regardless of its calibre. In most cases the connection end to side is desirable or preffered.
In the case of anastomozes in small calibre area. which generally means the diameter up to 6 mm (for example the reconstruction of coronary arteries), there exists certain problem, occuring relatively often after some time-period, usually after several months, and has no dependence on the technical quality of the performed anastomosis. It is the phenomenom standartly described as the intimo-medial hyperplasia. It means, that in the connection, most commonly in the apex of the anastomosis, gradually develops a mound consisting from the structures of the hyperplastic intima and media of the targeted vessel, it means of the vessel, on which the connection is created in the direction of a blood flow. The situation is best ilustrated on the Fig. 1., where is the schematic drawing of the anastomosis of the vessel 1 and vascular substitute 2 end to side and in typical localization is demonstrated the intimo-medial hyperplasia 3 and by the arrow → is indicated the blood flow.
This gradually growing structure (3a,3b) understandably leads to the stenosis of the cross-section of the reconstruction, reduction of the blood flow and ultimately to the complete occlusion.
The generally accepted theory of the development of this the created anastomosis disturbs,
phenomenom is as follows : the created anastomosis disturbs, in dependence on different circumstances, the different characteristics of blood flow, most commonly so called stability of the flow, which is expressed by Reynolds' number. The anastomosis also disturbs the normal laminal flow toward turbulence. In the direct relation the higher turbulence means also the higher quantity of liberated energy. The forces, which activate the perivascular transfer of the energy by a vibration across the vascular wall simultaneously are the cause of the chronical stress and damage of the surrounding tissue and in the same time initiate the response of biochemical mediators and in their ultimate effect lead to the gradual development of the intimo-medial hyperplasia.

In the present time there is known no method, in the accessible literature, which could prevent this undesirable biological process with some degree of reliability. The most common preventive measure is the creation of maximally wide anastomosis. This possibility is of course objectively limited by the calibre of connected tubes, either vessels, either vessel and substitute. The internal reinforcement of the created anastomosis by a stiff lining in accordance with the invention eliminates the pricipal cause of the intimo-medial hyperplasia - the perivascular transfer of the energy liberated by the turbulence accross a soft vascular wall with the permanent vibrational stress and subsequent tissue reaction.

The principle of the invention

The device in accordance with the invention is presented by the semitubular formation of the diameter comensurate to the diameter of targeted vessel or substitute, created from a stiff , tightly elastic, sterilizable, biologically inert and unmoistenable material and of such a length, so the most commonly affected locations are lined. In the third and fourt fifth of the length (counted counter to the direction of the blood flow) on the convexity of the tube is formed an orifice, corresponding by its length minimally to the double of the diameter of the targeted vessel and by its width minimally to the quarter of the circumference of the said vessel. From the apex of this orifice (in the direction of the blood flow) grows in the angle 20-45 degrees counter to the blood flow, the tongue-like structure of the length minimal twice of the diameter of the targeted vessel and of such a form, that it gradually spreads into margins of the orifice so, that this transition does not exceed the third of the length of the orifice from the base of the tongue-like structure counter to the blood flow. The margins of the orifice are formed so, that they are moderately deviated externally on the top, as well as the tongue-like structure, which as a whole is also moderately deviated externally. On both sides of the margin in the middle of its length, frontaly ahead of the base of the tongue-like structure and in the rear behind the end of the orifice are created always two small holes for fixation sutures on the targeted vessel or substitute in such way, that these fixating sutures can be employed in the sufficient distance from the margins of an open vessel, so the anastomosis can be executed distally from the orifice of the device.

In some rare cases the development of the intimo-medial occurs on the rear of the anastomosis (counter to the blood flow). For these cases is created the device on the same principle, but with the tongue-like structure into the inflowing vessel or substitute under the same angle, but arising from the rear end of the orifice in the device and with a gradual transition into margins of the

orifice, but not exceeding one third of the legth of the orifice.

By the combination of both solutions it is possible to create the double-tongue device with one tongue-like structure growing into the legth minimally twice of the diameter of the targeted vessel or substitute from the apex of the orifice of the device and with one tongue-like structure growing from the rear end of the orifice, both of the same length and under the same angle 20 - 45 degrees.

In all cases the material used has to be non-resorbable, sterilizable, biologically inert, unmoistenable, stiff or moderately elastic either by itself (stainless steel, carbonic steel, carbonic composites, glass, synthetic materials) or in different physical or chemical combination, most commonly in the form of coating (stainless steel coated by graphit, synthetic base coated by titan etc.).

Simultaneously with the securing of the proper structural stability, the device is maximally thin-walled with all margins blunt.

The summary of the pictures on drawings

On the Fig. 1 is schematically ilustrated the typical localization of intimo-medial hyperplasia. On the Fig. 2 is schematically drawn the typical locating of the internal shield in an anastomosis. On the Fig. 3 is illustrated the whole device with its typical characteristics. On the Fig. 4 is illustrated the detail of the margin of the orifice and of the base of the tongue-like structure. On the Fig. 5 is illustrated the dimensional relation of individual parts of the device and the angle of the growing-up of the tongue-like structure. On the Fig. 6 is illustrated the device with the tongue-like structure growing-up from the rear end of the orifice. On the Fig. 7 is illustrated the device with the tongue-like structures growing up from the apex as well as the rear end of the orifice.

The examples of the execution of the invention

1. From the thin-walled carbonic steel is formed an uncomplete tube 4 in the form of two thirds of the circumference of diameter 6 mm. This uncomplete tube forms the body 4 of the device and its entire length is minimally 30 mm, when the first . two fifths of the length are entire, as well as the last fifth. In the third and fourth fifth is on the convexity formed the eliptic oriifice 5 wide minimally 5 mm measured on the circumference. From the apical end of this orifice 5 grows up under the angle 20-45 degrees the tongue-like structure 6 at the base wide minimally 5 mm, moderately bow-like curved externally and gradually tapered toward the tip with the minimal legth in the central axis 12 mm. This tongue-like structure 6 is at its base moderately spreaded and transits gradually by its foot 7 into the margin 8 of the orifice 5. Outside of the margin 8 of the orifice 5 are in the distance minimally 2 mm located pairs of small holes 9 for the placing, of the fixation sutures on the wall of the targeted vessel or substitute. The whole internal surface is highly polished and the margins are blunt.

2. The device with all characteristics of the device under point 1, but the margins 8 of the orifice 5 are formed in such way, that they are moderately turned externally (8a) and by the same way is adjusted the external surface of the base of the tongue-like structure 6.

3. The device manufactured from the thin-walled stainless steel with the body 4 minimally 30 mm long, where from the rear end of the or4fice 5 grows up the tongue-like structure 1C in the angle 30 degrees counter to the blood flow. The whole internal surface of the device is coated by a thin layer of graphit.

4. The device manufactured from teflon, which body 4 minimally 30mm long and from the margin 8 of the orifice 5 grows -up one tongue-like structure 6 from the apical end counter to the blood flow under the angle 30 degrees and of length minimally 12 mm and from the rear end of the same orifice 5 grows up the similar tongue-like structure 10 under identical angle and with the identical length as is the tongue-like structure 6 of the said device. The whole internal surface of the shield is coated by a thin layer of titan and is highly polished.

Claims

1 . The device for the internal shielding of a vascular anastomomosis end to side characterized by the fact, that is created from a stiff, eventually moderately elastic, biologically inert, unmoistenable, nonresorbable, sterilizable single or combined multielemental material, having the form of the uncomplete two-third tube 4, which length is minimally five times value of the diameter of the complete tube and in which third and fourth fifth counter to the blood flow is on the convexity formed -the orifice 5 of the length minimally double of the diameter of the complete tube and which width is minimally one quarter of the circumference of the tube, while from the apex of the orifice 5 grows up under the angle 20 to 45 degrees counter to the course of blood flow gradually tapered tongue-like structure 6 at foot wide minimally one quarter of the circumference of the tube, gradually transgressing by the foot 7 into margin 8 of the orifice 5, so the whole transition does not exceed one third of the orifice 5 and the whole said tongue-like structure 6 is in the longitudinal axis moderately bow-like curved externally, as well as is the margin 8 @f the orifice 5, which is also moderately curved externally and when all margins are blunt and the whole internal surface is highly polished.

2. The device for the internal shielding of a vascular anastomosis end to side characterized by the fact, that is created from a stiff, eventually moderatelly elastic, biologically inert, unmoistenable, non-resorbable,sterilizable single or combined multielemental material, having the form of the uncomplete two-third tube 4, which length is minimally five times value of the diameter of the complete tube and in which third and fourth fifth counter to the course of blood flow is on the convexity formed the orifice 5 of the length minimally double of the diameter of the complete tube and which width is minimally one quarter of the circumference of the tube, while from the rear end of the said orifce 5 grows up under the angle 20 to 45 degrees counter to the course of blood flow gradually tapered tongue-like structure 10 at a foot wide minimally one quarter the circumference of the tube, gradually transgressing by the foot 11 into the margin 8 of the orifice 5, so the whole transition does not exceed one third of the length of the orifice 5 and the whole said tongue - like structure 10 is in the longitudinal axis moderately bow-like curved externally as well as is the margin 8 of the orifice 5, which is also moderately curved externally and when all mergins are blunt and the whole internal surface is highly polished.

3. The device for the internal shielding of a vascular anastomosis end to side characterized by the fact, that is created from a stiff, eventually moderately elastic, biologically inert, unmoistenable, non-resorbable, sterilizable, single or combined multi-elemental material, having the form of the uncomplete two-third tube 4, which length is minimally five times value of the diameter of the complete tube and in which third and fourth fifth counter to the course of blood flows on the convexity formed the orifice 5 of the length minimally double of the diameter of the complete tube and which width is minimally one quarter of the circumference of the tube, while from the apex of the orifice 5 grows up under the angle 20 to 45 degrees counter to the course of the blood flow gradually tapered tongue-like structure 6 at foot minimally one quarter of the circumference of the tube, gradually transgressing by the foot 7 into margin 8 of the orifice 5, so the whole transition does not exceed one third of the length of the orifice 5 and simultaneously from the rear end of the orifice 5 grows up under the angle 20 to 45 degrees gradually tapered tongue-like structure 10 at foot wide minimally one quarter of the circumference of the tube, gradually transgressing by the foot 11 into the margin 8 of the orifice 5 so the whole,transition does not exceed on third of the length of the orifice 5, while the tongue-like structure 6 growing up from the apex of the orifice 5 as well as the tongue-like structure 10, growing up from the rear end of the orifice 5 are both moderately bow-like curved externally, as well as the margin 8 of the orifice 5, which is also moderately curved externally, while all margins are blunt and the whole internal surface is highly polished.

. The device in accordance with the claim 1, 2 and 3 characterized by the fact, that in the middle of the length of the orifice 5 on both sides, like in the front of the apical end of the orifice 5 and also dorsaly f rom the rear end of the orifice 5, in the distance minimally 2 mm from the top of margin 8 are placed pairs of small holes 9 for the fitting of fixation sutures between the device and the targeted vessel or substitute.

The device in accordance with the claims 1, 2, 3 and 4 characterized by the fact, that close to the tips of the tongue-like structures 6 and/or 10 are placed pairs of small holes 12 for the fitting of the fixation sutures between these tongue-like structures abd the vessel or the substitute into which they are slipped.

. The device in accordance with the claims 1 , 2 , 3 , 4 and 5 characterized by the fact, that the internal surface of the said device is equiped with the physically or chemically bounded pharmacologically active matter.

7. The device in accordance with the claims 1, 2, 3, 4, 5 and 6 characterized by the fact, that the external surface of the device is equiped with the physically or chemically bounded pharmacologically active matter.

8. The biological or arteficial vascular substitute characterized by the fact, that the device in the accordance with the claims 1, 2, 3, 4, 5, 6 and 7 is provided in the said substitute as its integral part by its manufacturer.

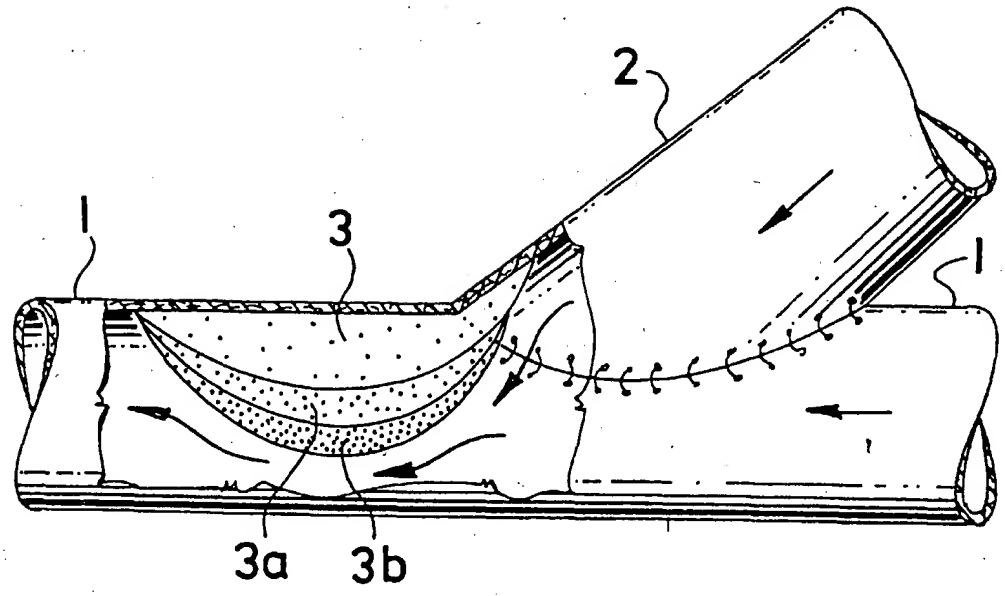

Fig. 1

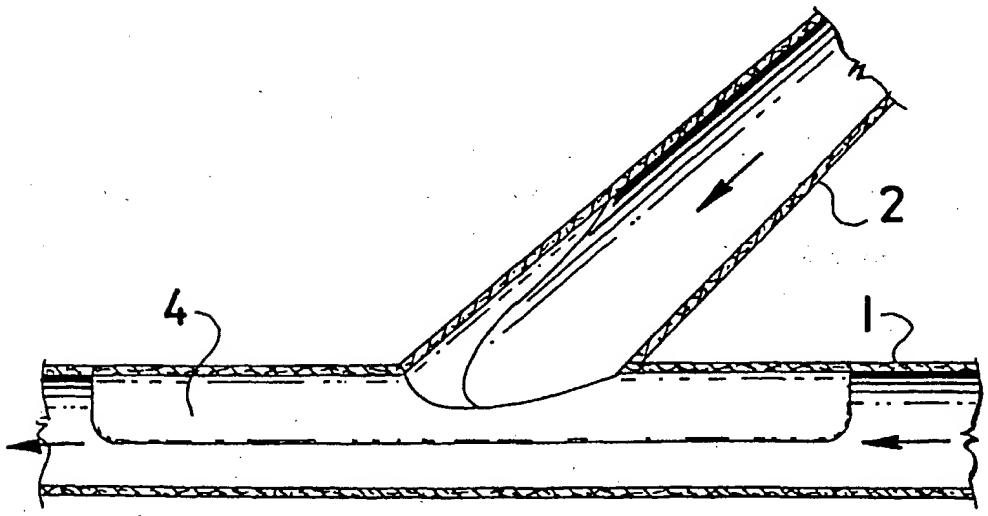

Fig. 2

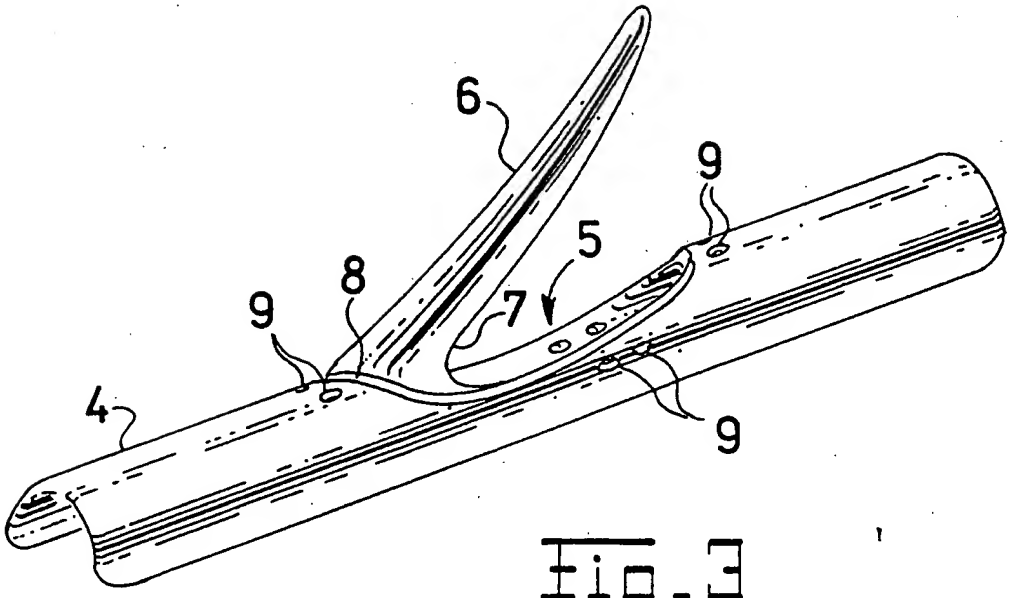

Fig. 3

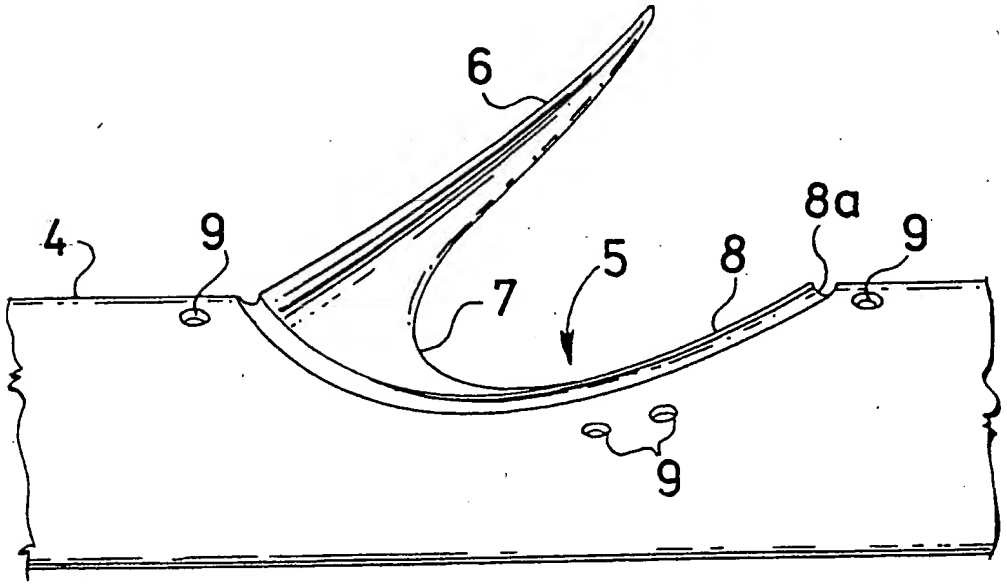

Fig. 4

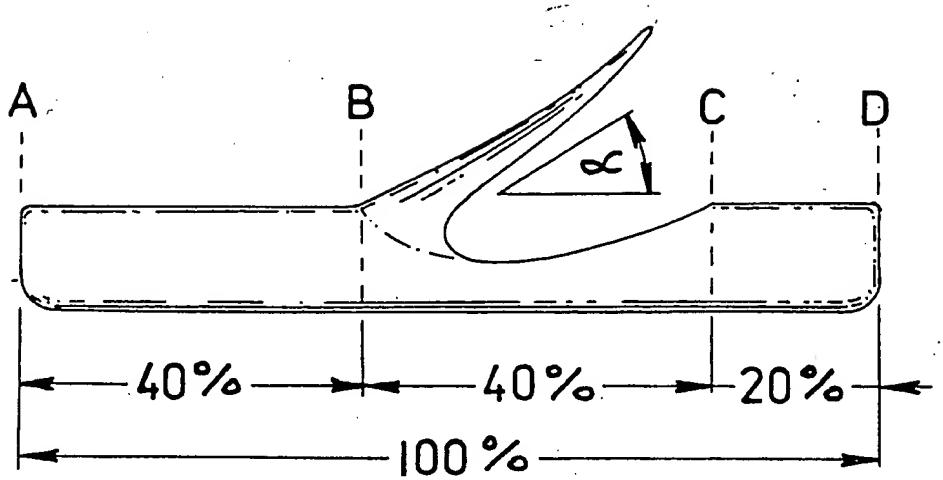

Fig. 5

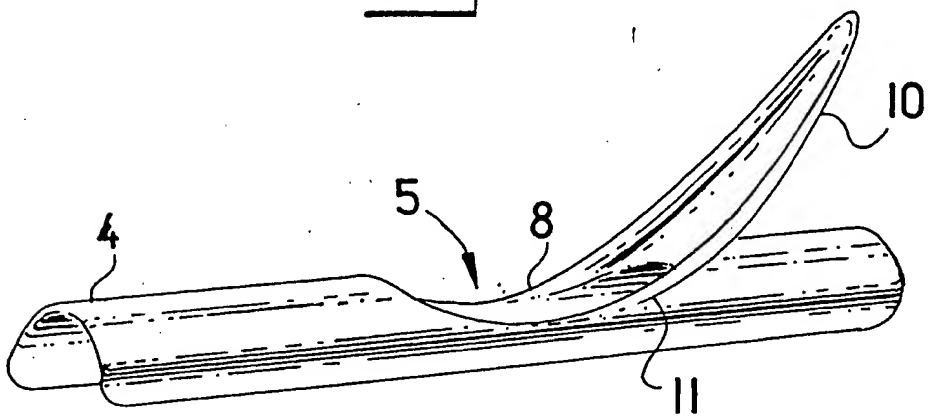

Fig. 6

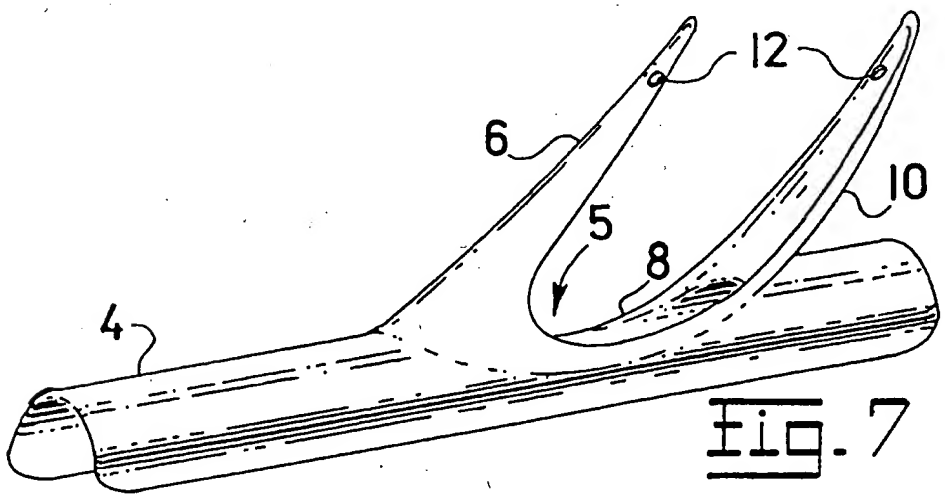

Fig. 7

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(54) Internal shield for a vascular anastomosis

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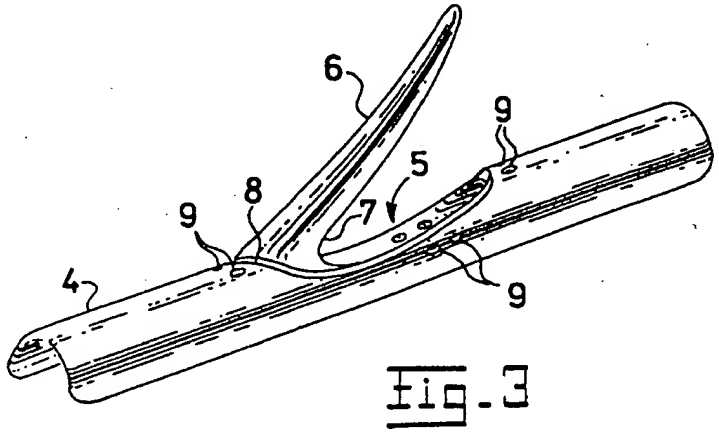

Fig. 3

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EUROPEAN SEARCH REPORT

Application Number
EP 97 25 0238

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	US 5 156 619 A (EHRENFELD) * abstract; figures *	1-3	A61F2/06 A61B17/11
A	EP 0 709 066 A (NUNOKAWA) * abstract; figures *	1-3	
A	US 4 313 231 A (KOYAMADA)		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61F
A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	24 April 1998	Hagberg, A

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